IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

BAILEY SILVERMAN and LOUIS SILVERMAN	§	
Plaintiffs	§	
V.	§	**CASE NO. 4:10-cv-1952**
WATSON LABORATORIES; INC.- Florida, and WATSON PHARMA, INC.	§	
Defendants.	§	

ANSWER OF DEFENDANT WATSON LABORATORIES, INC.- FLORIDA TO PLAINTIFF'S FIRST AMENDED COMPLAINT

NOW COMES Defendant Watson Laboratories, Inc.- Florida[1] ("Defendant" or "Watson Laboratories") and files this its Answer in response to Plaintiffs' First Amended Complaint ("Amended Complaint"), and would respectfully show the Court as follows:

THE PARTIES

1. In response to paragraph 1 of the Amended Complaint, Watson Laboratories denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth therein regarding Plaintiffs' residence. Watson Laboratories denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations in the remainder of paragraph 1 of the Amended Complaint.

2. In response to paragraph 2 of the Amended Complaint, Watson Laboratories admits that that it manufactures and sells certain prescription medications

[1] Pursuant to the agreement of counsel, dated December 20, 2010, Plaintiffs' first amended complaint substituted Watson Laboratories, Inc.- Florida as defendant in place and stead of Watson Pharmaceuticals, Inc. and Watson Pharmaceuticals, Inc. New Jersey.

and that it has appeared in this action, Defendant otherwise denies the allegations set forth in paragraph 2 and denies knowledge or information sufficient to sufficient to form a belief as to the truth or falsity of the allegations to the extent such allegations refer or relate to defendants other than the answering Defendant.

JURISDICTION

3. In response to paragraph 3 of the Amended Complaint, Watson Laboratories, Inc. admits that it manufactured and sold in interstate commerce the prescription medication Taztia XT, including in the State of Texas, but denies each and every remaining allegation in paragraph 3 of the Amended Complaint, and denies knowledge or information sufficient to sufficient to form a belief as to the truth or falsity of the allegations to the extent such allegations refer or relate to defendants other than the answering Defendant.

4. In response to paragraph 4 of the Amended Complaint, Watson Laboratories denies each and every allegation in paragraph 4 of the Amended Complaint, and denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth therein regarding the events giving rise to this suit. .

FACTS

5. In response to paragraph 4 of the Amended Complaint, Watson Laboratories admits that Taztia XT (diltiazem hydrochloride) is a prescription medication for use in accordance with the indications set forth in its FDA-mandated and approved labeling and, except as expressly set forth therein, denies each and every allegation set for in paragraph 5 of the Amended Complaint.

6. In response to paragraph 6 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein, except admits that Watson Laboratories manufactures and sells generic diltiazem in dosage form for human use.

7. In response to paragraph 7 of the Amended Complaint, Watson Laboratories denies each and every allegation to the extent such allegations purport to refer or relate to Watson Laboratories, and to the extent such allegations purport to state conclusions of medical or scientific fact, neither admit nor deny such allegations and demand strict proof thereof.

8. In response to paragraph 8 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein.

9. In response to paragraph 9 of the Amended Complaint, Watson Laboratories admits that it complied with all applicable state and federal laws and regulations including the Food, Drug & Cosmetic Act in connection with the manufacture and sale of its products and otherwise denies each and every allegation contained therein.

10. In response to paragraph 10 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein.

11. In response to paragraph 11 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein.

12. In response to paragraph 12 of the Amended Complaint, Watson Laboratories denies each and every allegation therein.

13. In response to paragraph 13 of the Amended Complaint, Watson Laboratories denies each and every allegation therein.

14. In response to paragraph 14 of the Amended Complaint, Watson Laboratories admits that it complied with all applicable state and federal laws and regulations including the Food, Drug & Cosmetic Act in connection with the manufacture and sale of its products and otherwise denies each and every allegation contained therein.

15. In response to paragraph 15 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein.

16. In response to paragraph 16 of the Amended Complaint, Watson Laboratories denies each and every allegation therein.

FACTS REGARDING PLAINTIFF BAILEY SILVERMAN

17. In response to paragraph 17 of the Amended Complaint, Watson Laboratories denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained therein.

18. In response to paragraph 18 of the Amended Complaint, Watson Laboratories denies each and every allegation to the extent such allegations purport to refer or relate to Watson Laboratories, and to the extent such allegations purport to state conclusions of medical or scientific fact, neither admit nor deny such allegations and demand strict proof thereof.

19. In response to paragraph 19 of the Amended Complaint, Watson Laboratories denies each and every allegation to the extent such allegations purport to refer or relate to Watson Laboratories, and to the extent such allegations purport to

state conclusions of medical or scientific fact, neither admit nor deny such allegations and demand strict proof thereof.

20. In response to paragraph 18 of the Amended Complaint, Watson Laboratories denies each and every allegation to the extent such allegations purport to refer or relate to Watson Laboratories, and to the extent such allegations purport to state conclusions of medical or scientific fact, neither admit nor deny such allegations and demand strict proof thereof.

21. In response to paragraph 21 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein.

22. In response to paragraph 22 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein.

23. In response to paragraph 23 of the Amended Complaint, Watson Laboratories denies each and every allegation therein, including specifically:

a. Watson Laboratories denies each and every allegation therein.

b. Watson Laboratories denies each and every allegation therein.

c. Watson Laboratories denies each and every allegation therein.

d. Watson Laboratories denies each and every allegation therein.

e. Watson Laboratories denies each and every allegation therein.

f. Watson Laboratories denies each and every allegation therein.

COUNT ONE
Strict Liability

24. In response to paragraph 24 of the Amended Complaint, Watson Laboratories repeats and realleges each and every response to paragraphs 1 through 23 of the Amended Complaint as though hereinafter fully set forth at length.

25. In response to paragraph 25 of the Amended Complaint, Watson Laboratories admits that manufactured and sold the prescription medication Taztia XT, but denies each and every remaining allegation in paragraph 25 of the Amended Complaint.

26. In response to paragraph 26 of the Amended Complaint, Watson Laboratories denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained therein.

27. In response to paragraph 27 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein.

28. In response to paragraph 28 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein.

29. In response to paragraph 29 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein.

30. In response to paragraph 30 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein.

31. In response to paragraph 31 of the Amended Complaint, Watson Laboratories denies each and every allegation therein, including specifically:

a. Watson Laboratories denies each and every allegation therein.

b. Watson Laboratories denies each and every allegation therein.

c. Watson Laboratories denies each and every allegation therein.

d. Watson Laboratories denies each and every allegation therein.

e. Watson Laboratories denies each and every allegation therein.

f. Watson Laboratories denies each and every allegation therein.

g. Watson Laboratories denies each and every allegation therein.

h. Watson Laboratories denies each and every allegation therein.

i. Watson Laboratories denies each and every allegation therein.

j. Watson Laboratories denies each and every allegation therein.

32. In response to paragraph 32 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein to the extent such allegations purport to refer or relate to the conduct of Watson Laboratories, and denies knowledge and information sufficient to form a belief as to the truth or falsity of the allegations regarding Plaintiffs' ability to discover or perceive dangers.

33. In response to paragraph 33 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein.

34 In response to paragraph 34 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein.

COUNT TWO

Breach of Implied Warranty

35. In response to paragraph 24 of the Amended Complaint, Watson Laboratories repeats and realleges each and every response to paragraphs 1 through 34 the Amended Complaint as though hereinafter fully set forth at length.

36. In response to paragraph 36 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein.

37. In response to paragraph 37 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein.

38. In response to paragraph 38 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein.

39. In response to paragraph 39 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein.

COUNT THREE
Negligence

40. In response to paragraph 40 of the Amended Complaint, Watson Laboratories repeats and realleges each and every response to paragraphs 1 through 39 the Amended Complaint as though hereinafter fully set forth at length.

41. In response to paragraph 41 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein, answering further Watson Laboratories complied with all applicable state and federal laws and regulations including the Food, Drug & Cosmetic Act.

42. In response to paragraph 42 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein, answering further Watson Laboratories complied with all applicable state and federal laws and regulations including the Food, Drug & Cosmetic Act.

43. In response to paragraph 43 of the Amended Complaint, Watson Laboratories denies each and every allegation therein, including specifically:

a. Watson Laboratories denies each and every allegation therein.

b. Watson Laboratories denies each and every allegation therein.

c. Watson Laboratories denies each and every allegation therein.

d. Watson Laboratories denies each and every allegation therein.

e. Watson Laboratories denies each and every allegation therein.

f. Watson Laboratories denies each and every allegation therein.

g. Watson Laboratories denies each and every allegation therein.

h. Watson Laboratories denies each and every allegation therein.

i. Watson Laboratories denies each and every allegation therein.

j. Watson Laboratories denies each and every allegation therein.

k. Watson Laboratories denies each and every allegation therein.

44. In response to paragraph 44 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein.

45. In response to paragraph 45 of the Amended Complaint, Watson Laboratories denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations and therefore denies such allegations.

46. In response to paragraph 46 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein.

47. In response to paragraph 47 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein.

48. In response to paragraph 48 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein.

COUNT FOUR
Loss of Consortium

49. In response to paragraph 49 of the Amended Complaint, Watson Laboratories repeats and realleges each and every response to paragraphs 1 through 48 the Amended Complaint as though hereinafter fully set forth at length.

50. In response to paragraph 50 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein.

COUNT FIVE
Punitive or Exemplary Damages

51. In response to paragraph 51 of the Amended Complaint, Watson Laboratories repeats and realleges each and every response to paragraphs 1 through 50 the Amended Complaint as though hereinafter fully set forth at length.

52. In response to paragraph 52 of the Amended Complaint, Watson Laboratories denies each and every allegation contained therein.

JURY DEMAND

Watson Laboratories agrees that a jury trial is appropriate in this matter.

PRAYER FOR RELIEF

In response to Plaintiffs' enumeration of damages in its prayer for relief section of the Complaint, Watson Laboratories denies that it is liable to Plaintiffs for any of the enumerated items of damages, and further specifically denies that any injuries or damages suffered by Plaintiffs resulted from culpable conduct of Watson Laboratories.

AFFIRMATIVE DEFENSES

1. Plaintiffs' Amended Complaint, and each and every allegation therein directed to Watson Laboratories, fails to state a claim against Watson Laboratories upon which relief may be granted.

2. Plaintiffs' claims are barred in whole or in part by the applicable statutes of limitations.

3. Plaintiffs' claims against Watson Laboratories are barred by laches, waiver, and/or estoppel.

4. If Plaintiffs sustained any injury or incurred any loss or damage as alleged in the Amended Complaint, the same resulted in whole or in part from an intervening cause and/or causes, and any action on the part of Watson Laboratories was not the proximate and/or competent producing cause of Plaintiffs' alleged injuries.

5. If Plaintiffs sustained any injury or incurred any loss or damages as alleged in the Amended Complaint, the same were caused in whole or in part by acts or omissions of another or others over whom Watson Laboratories neither exercised nor had any right of control, for which Watson Laboratories is and was not responsible, and whose conduct Watson Laboratories had no duty or reason to anticipate or control.

6. If in fact the Amended Complaint is held to contain a claim upon which relief may be granted, then Plaintiffs' recovery, if any, should be reduced by the relative amount of comparative fault attributable to Plaintiffs or their agents or persons other than Watson Laboratories.

7. Watson Laboratories' Taztia products were available only upon the prescription of a licensed physician, and the federal government has preempted the field of law applicable to prescription items and their labeling. The manufacture, marketing and labeling of Watson Laboratories' Taztia products were and are controlled by federal law and Watson Laboratories was at all times in compliance with applicable federal law with respect thereto; therefore, the Amended Complaint fails to state a claim upon which relief may be granted in that, *inter alia*, such causes of action, if upheld, would impede, impair, frustrate or burden the effectiveness of federal law regulating the

field of prescription items and would constitute an invalid burden by this court on interstate commerce, and would, therefore, violate the Supremacy Clause (Article VI, Section 2) and the Commerce Clause (Article I, Section 8) of the United States Constitution.

8. To the extent Plaintiffs' allegations claim that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, Defendant Watson Laboratories would assert that Texas Civil Practice & Remedies Code §82.007 is applicable and that the warnings provided with Watson Laboratories' Taztia products were those stated in monographs developed by the United States Food and Drug Administration for pharmaceutical products that may be distributed without an approved new drug application. Defendant Watson Laboratories is therefore entitled to a rebuttal presumption of no liability with respect to the allegations involving failure to provide adequate warnings or information.

9. In the event Plaintiffs are found to have suffered any injury, disease, damage, pain and/or disability, the degree of responsibility, negligence, and fault of each person who contributed to said injuries should be determined, and Watson Laboratories should be held liable only for that proportion of the resulting damage which corresponds to its degree of fault, responsibility, or negligence, if any.

10. Any damages, injuries or losses that may have been sustained by Plaintiffs as alleged in the Amended Complaint were sustained only after Plaintiffs knowingly and voluntarily assumed any alleged risk inherent in the use of Watson Laboratories' Taztia products.

11. Plaintiffs failed to heed the warnings provided by Watson Laboratories.

12. Upon information and belief, any injury, loss or damage that Plaintiffs may have sustained were caused in whole or in part by Plaintiffs' own negligence.

13. Defendant's liability, if any, should be limited by § 33.013 of the Texas Civil Practice & Remedies Code.

14. At all times relevant to Plaintiffs' claims against Defendant, Defendant conformed its conduct to the state of medical knowledge, common and accepted procedures in the medial field, professional standards, and the medical and pharmacological state of the art.

15. Plaintiffs' claims are barred, in whole or in part because the Defendant complied with all applicable statues and with the requirements and regulations of the Food and Drug Administration and the State of Texas.

16. Plaintiffs' claims against Defendant are barred under Section 402A, comment K of the *Restatement (Second) of Torts*.

17. Plaintiffs' claims against Defendant are barred under Sections 2, 4, and 6 *et seq*. of the Restatement (Third) of Torts: Products Liability.

18. Plaintiffs' purported breach of warranty claims are barred by (a) the absence privity of contract between Plaintiffs and Defendant; (b) Plaintiffs' failure to give timely notice of any alleged breach of warranty to Defendant; (c) Plaintiffs' lack of reasonable reliance on any alleged warranty; (d) Plaintiffs' failure to satisfy all conditions precedent or subsequent to the enforcement of any such alleged warranty; (e) disclaimer, exclusion or modification.

19. Any award of punitive damages against the Defendants would violate its right to due process of law under the United States Constitution Amend. XIV; its right to

due course of law under Art. I, § 19 of the Texas Constitution; its right to the equal protection of the law under Amend. XIV of the United States Constitution; and Art. I, § 3 of the Texas Constitution; its right to freedom from excessive fines and cruel and unusual punishment under Art. I, § 13 of the Texas Constitution; and its rights under the common law, statutes, rules of civil procedure, and public policy of the State of Texas, because under Texas law the jury:

(1) is not provided standards of sufficient clarity for determining the appropriateness, and appropriate size, of a punitive damage award;

(2) is not adequately instructed on the limits on punitive damages imposed by the applicable principles of deterrence and punishment (including the rule that punitive damages must be reasonably proportioned to actual damages);

(3) is not expressly prohibited from awarding punitive damages, or determining the amount of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including the national origin, residence, wealth, and corporate status of the defendant;

(4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; and

(5) is not subject to particularized, detailed, and objective trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes.

Additionally, said constitutional provisions, and the common law, statutes, rules of civil procedure, and public policy of the State of Texas, require:

(a) that Defendant's alleged liability for punitive damages in the amount of any such liability be determined by a standard of clear and convincing evidence;

(b) that Defendant's alleged liability for punitive damages in the amount of any such liability be tried only if and after [defendant's] liability for compensatory damages has been found;

(c) that evidence of Defendant's wealth not be admitted as bearing on whether or in what amount punitive damages should be assessed, or alternatively, if any such admission of evidence occur only if and after Defendant's liability for compensatory damages has been found;

(d) that punitive damages be limited to a reasonable amount, bearing a reasonable proportion to the compensatory damages for which Defendant is found liable; and

(e) that Defendant's liability for punitive damages be based solely on Defendant's conduct in connection with the specific occurrence made the subject of this lawsuit.

20. Defendants affirmatively plead that, in the event exemplary damages are awarded, such damages may not exceed two times the amount of economic damages plus an amount equal to any non-economic damages not to exceed $750,000, or $200,000, whichever is greater, pursuant to Texas Civil Practice & Remedies Code, § 41.008.

21. Defendants assert their right to a credit and to make an election of credit for purposes of a settlement entered into with one or more Defendants in this case pursuant to Texas Civil Practices & Remedies Code, § 33.014.

22. If Watson Laboratories is found liable to Plaintiffs for any non-economic loss allegedly suffered by Plaintiffs, such liability equals fifty percent or less of the total liability of all persons liable, and the aggregate liability of such other persons equals or exceeds fifty percent of the total liability. Accordingly, Watson Laboratories' liability, if any, to Plaintiffs for Plaintiffs' non-economic loss shall not exceed Watson Laboratories' equitable share determined in accordance with the relative culpability of each person causing or contributing to the total liability for such non-economic loss.

23. At all times relevant to Plaintiffs' claims against Watson Laboratories, Watson Laboratories conformed its conduct to the state of medical knowledge, common

and accepted procedures in the medical field, professional standards, and the medical and pharmacological state of the art.

24. Any alleged defect in Watson Laboratories' Taztia products could not have been detected or removed by a reasonable use of scientific procedures or techniques.

25. Plaintiffs' breach of warranty claims are barred by Plaintiffs' failure to provide timely notice of any alleged breach of warranty.

26. Plaintiffs' breach of warranty claims are barred by the absence of privity between Plaintiffs and Watson Laboratories.

27. At all times, Watson Laboratories' Taztia products were available only upon the prescription of a licensed physician. Upon information and belief, Plaintiff's prescribing physicians were aware of all risks that were known or could have been known to be associated with the use of Watson Laboratories' Taztia products in accordance with their indications and product use instructions. Accordingly, Plaintiffs' claims are barred wholly or in part by the learned intermediary defense.

28. Plaintiffs have failed to join and include in this action all identifiable and indispensable parties without whom, in equity and fairness, this action should not proceed.

29. Plaintiffs' claims are barred in whole or in part by the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution, as well as by the Texas State Constitution.

30. Any injuries, damages and/or losses allegedly sustained by Plaintiffs were caused in whole or in part by preexisting conditions, for which Watson Laboratories bears no legal responsibility or liability.

31. Upon information and belief, some or all of Plaintiffs' damages will be replaced or indemnified, in whole or in part, from collateral sources, and Watson Laboratories is therefore entitled to a collateral source offset.

32. Plaintiffs have failed to state a claim against Defendant upon which relief may be granted for punitive or exemplary damages.

33. Plaintiffs' claims are barred in whole or in part by the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution, as well as by the applicable state Constitution.

34. Watson Laboratories reserves the right to raise such further and additional defenses as may be available upon the facts to be developed in discovery and under applicable substantive law.

Respectfully submitted,

S/ Michael A. Walsh
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Watson Laboratories, Inc. – Florida and
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CERTIFICATE OF SERVICE

This is to certify that on January 10, 2011, I electronically filed the foregoing document with the Clerk of the Court for the U.S. District Court, Southern District of Texas, using the electronic case filing system of the court. The electronic case filing system sent a "notice of Electronic Filing" to the following attorneys of record who have consented in writing to accept this Notice as service of this document by electronic means:

s/ Michael A. Walsh
MICHAEL A. WALSH